

REMARKS

Claim 1 has been amended to incorporate a recitation from claim 2, and claim 2 has been canceled accordingly. Claims 3 and 6 have been amended to change their dependency from canceled claim 2 to claim 1. Claim 3 has also been amended for consistency with claim 1.

Entry of the above amendment is respectfully requested.

PTO/SB/08 Form

Preliminarily, Applicants note that the Examiner has attached to the Office Action a PTO/SB/08 form on which he indicates that the reference was not considered because no copy was provided.

On review, Applicants note that a copy of the reference can be seen in the Image File Wrapper of the PAIR system on the PTO website under the heading "Foreign Reference" with a mail room date of June 20, 2008. Accordingly, Applicants respectfully request that the Examiner consider the reference and return an initialed PTO/SB/08 form with the next communication from the PTO.

Obviousness Rejection

On page 3 of the Office Action, in paragraph 7, claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue, et al. (WO 2004/067521 A1) and Ogata et al. (US 4,780,465; 1988).

In response, Applicants note initially that claim 1 has been amended so that the compound of formula (I) is limited to those having a guanidyl group at the terminal (Z).

Applicants further note that this amendment is supported by original claim 2, as well as test examples, and Applicants submit that the amended claims are not obvious over the cited art for at least the reasons set forth below.

1) Applicants submit that the scope of the compound of the instant invention is quite different from Inoue. In the instant application, the compound is limited to those having the guanidyl group at the terminal. An inventive feature of the instant application is in the fact that the solubility of the specific compound that has a guanidyl group at the terminal in water is significantly deteriorated by the presence of NaCl and that the deterioration is not a function of pH of the aqueous solution but the structure of the terminal group of the compound (Test Example 1). Based on the findings, the Applicants have achieved the present invention.

Inoue is silent about the above discussed feature of the specific compound. On page 28, lines 10-12, Inoue suggests the use of saline (= NaCl) as an isotonic agent in addition to glucose. Therefore, the art would not be motivated to chose an additive from the group of polyol, sugar alcohol, boric acid and a salt of boric acid for manufacturing the aqueous composition comprising the specific compound of the instant application.

2) The solubility of the specific compound of claim 1 in water is also significantly deteriorated by the presence of not only NaCl but also other ionic components such as potassium chloride, disodium hydrogenphosphate and sodium citrate (see Example 2 of the specification). Accordingly, the list of the additives of the instant invention does not comprise any ionic component. However, Inoue does not mention this property and, therefore, the art would not be motivated to choose an isotonic agent or an additive from the group that does not comprise an ionic component.

3) Applicants note the Examiner indicates that Ogata (US4780465) teaches NaCl, glycerin, mannitol, boric acid and glucose are isotonic agents for aqueous solutions. However, the structure of the compound disclosed in Ogata is completely different from the instant invention. Under the presence of NaCl, the quinolone carboxylic acid exhibits a diminished solubility in water only when the pH of the solution is 3-6.5. In contrast, the solubility in water of the compound recited in the instant claim 1 is always decreased, when NaCl is present irrespective of the pH of the aqueous solution. The decrease of the solubility is caused by the presence of the guanidyl group at the terminal of the compound. The difference of chemical structures will greatly affect the physiochemical properties of the compound. Accordingly, the art would not come up with the idea to apply the isotonic agents for quinolone carboxylic acid in Ogata for manufacturing an aqueous composition comprising the compound of formula (I) of the present application.

4) Since Inoue does not even suggest the object of the present invention, i.e., preparing a clear and stable aqueous composition comprising the specific compound of the instant invention whose solubility in water will be decreased in the presence of an ionic component, the instant claims are patentable over the cited art.

Thus, Applicants submit that the present claims should not be rejected over the cited art, and withdrawal of this rejection is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

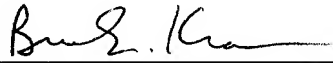
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